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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,389	09/15/2004	Werner Zumbrunn	095473-0106	5388

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FOLEY AND LARDNER LLP
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

MERCIER, MELISSA S

ART UNIT	PAPER NUMBER
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1615

MAIL DATE	DELIVERY MODE
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02/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/711,389	Applicant(s) ZUMBRUNN ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 1-16, 19, 24, 25, 27-32, 36 and 37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-18, 20-23, 26, 33-35, 38-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10-27-09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Summary

Receipt of Applicants Remarks and Amended Claims filed October 7, 2009 is acknowledged. Claims 1-39 are pending in this application. Claims 1-16, 19, 24, 25, 27-32, 36-37 remain withdrawn from consideration. Claims 17-18, 20-23, 26, 33-35, and 38-39 are under prosecution in this application.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on October 27, 2009 is acknowledged. A signed copy is attached to this office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

The rejection of claims 23 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of Applicants amendment to the claim to remove the recitation of 14.

Maintained Rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-18, 20-23, 26, 35, and 38-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Murdock (US Patent 6,374,136).

Murdock discloses an electrode assembly and a method of forming an anhydrous reservoirs layer of an electrode assembly in an electro transport transdermal agent delivery device. The reservoir layer is adapted to be placed in agent transmitting relation with a body surface and an electrode in electric contact with a power source and the reservoir layer. The method includes the steps of dissolving a beneficial agent in a solvent, applying the solvent and dissolved beneficial agent to a surface of a hydrophilic polymer filtration membrane, removing the solvent from the surface of the filtration membrane and disposing the beneficial agent/filtration membrane with the electrode assembly (abstract). The solvent can be removed from the polymer membrane by drying the membrane in a forced air oven, a vacuum drying oven, a desiccators, or by lyophilizing the polymer membrane (column 5, lines 48-51).

Applicant has identified the porous structure to be skin; therefore, application of the transdermal patch meets the limitation of arranged in the vicinity of the porous surface.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murdock (US Patent 6,374,136) in view of Haak et al. (US Patent 5,993,435).

The teachings of Murdock are discussed above and applied in the same manner.

Murdock does not disclose the use of sensors.

Haak discloses an iontophoretic delivery device comprising a selectively permeable membrane positioned between the agent reservoirs and electrode (abstract).

A control circuit is optionally provided. It may take the form of an on-off switch for on demand drug delivery, a timer, a fixed or variable electrical resistor and a controller which automatically turn the device on and off at some desired periodicity to match the natural or circadian patterns of the body (column 10, lines 57-60). The control circuit may include an integrated circuit which could be designed to control the dosage of beneficial agent, or to respond to sensor signals in order to regulate the dosage to maintain a predetermined dosage regimen (column 11, lines 3-7).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the circuit control of Haak into the device of Murdock in order to control the dosage of the beneficial agent and to regulate the dosage to maintain a predetermined dosage as described by Haak.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.
Applicant argues:

***The reference discloses the making of the device and not the use of the device.**

The claims are drawn to the device and not a method of using. The device comprises the elements recited in the instant claims. Therefore, absent a showing of evidence to the contrary, it is the position of the Examiner that it would necessarily perform the functional properties as those disclosed in the instant claims.

***Haak does not disclose a sensor for measuring a condition of the at least one active substance.**

The Examiner respectfully disagrees. The sensors are disclosed to be useful for monitoring the blood sugar level for controlled administration of insulin, as argued by Applicant. The Examiner has interpreted such a monitoring to meet the limitation of measuring a condition of the at least one active substance, since blood glucose levels rise and fall in relation to the amount of insulin present in the blood stream.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA S. MERCIER whose telephone number is

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(571)272-9039. The examiner can normally be reached on 8:00am-4:30pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615